

AMENDED IN ASSEMBLY JUNE 26, 2006

AMENDED IN ASSEMBLY JUNE 21, 2005

AMENDED IN SENATE APRIL 28, 2005

AMENDED IN SENATE APRIL 11, 2005

## SENATE BILL

**No. 380**

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Introduced by ~~Senator Alquist~~ *Senators Alquist and Ashburn*

February 17, 2005

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~~An act to add Article 7 (commencing with Section 111657) to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, relating to drugs.~~ *An act to add Chapter 12.87 (commencing with Section 18987.7) to Part 6 of Division 9 of the Welfare and Institutions Code, relating to foster care.*

### LEGISLATIVE COUNSEL'S DIGEST

SB 380, as amended, Alquist. ~~Drugs: adverse event reporting.~~  
*Foster care: residentially based services: group homes.*

Existing law provides for child welfare services, which are public social services directed toward, among other purposes, protecting and promoting the welfare of all children, including those in foster care placement. Existing law provides for the placement of children in foster care in various settings, including group homes, by foster placement agencies, under the oversight of the State Department of Social Services.

Existing law provides for the Aid to Families with Dependent Children-Foster Care (AFDC-FC) program, under which, pursuant to a combination of federal, state, and county funds, aid on behalf of eligible children is paid to foster care providers.

Existing law, the California Community Care Facilities Act, provides for the licensure and regulation of community care facilities, including group homes, by the State Department of Social Services.

Existing law requires the State Department of Social Services, under the direction of the California Health and Human Services Agency and in collaboration with other appropriate organizations, as specified, to reexamine the role of out-of-home placements currently available for children served within the child welfare services system.

This bill would require the State Interagency Team for Children and Youth, within the California Health and Human Services Agency, to develop a plan for transforming the current system of group care for foster children or youth and for children with serious emotional disorders into a system of residentially based services. The bill would require that the plan contain specified elements, including elements relating to the services required to be offered by residentially based programs, administrative oversight of programs, the placement and assessment of children and youth in those programs, the use of available funding, agreements to test alternative program design and funding models, and the issuance by the State Department of Social Services of waivers with respect to regulatory provisions to implement those agreements. The bill would further require that the plan be submitted to the Legislature by July 1, 2008.

The bill would appropriate \$500,000 from the General Fund to the California Health and Human Services Agency for the purpose of employing an outside consultant with demonstrated national expertise in statewide foster care and residential systems.

~~The Sherman Food, Drug and Cosmetics Law provides for the regulation of various subjects relating to the processing, labeling, advertising, and sale of food, drugs, and cosmetics under the administration of the State Department of Health Services. A violation of these provisions is a crime.~~

~~This bill would require a licensed health professional and a health facility to report all suspected serious adverse drug events that are spontaneously discovered or observed in medical practice to MedWatch, the drug safety information and adverse event reporting program operated by the federal Food and Drug Administration (FDA), using the FDA 3500 Voluntary form developed by the FDA for MedWatch. The bill would prohibit a licensed health professional or health facility that violates this provision from being subject to the~~

~~existing penalties and remedies of the Sherman Food, Drug and Cosmetics Law or any other provision of law.~~

Vote: majority. Appropriation: no. Fiscal committee: ~~no~~ yes.  
State-mandated local program: no.

*The people of the State of California do enact as follows:*

1     *SECTION 1. Chapter 12.87 (commencing with Section*  
2     *18987.7) is added to Part 6 of Division 9 of the Welfare and*  
3     *Institutions Code, to read:*

4  
5     *CHAPTER 12.87. REFORM OF RESIDENTIALLY BASED SERVICES*  
6     *FOR CHILDREN AND YOUTH*

7  
8     *18987.7. (a) The State Interagency Team for Children and*  
9     *Youth, within the California Health and Human Services Agency,*  
10    *shall develop a plan for transforming the current system of group*  
11    *care for foster children or youth and for children with serious*  
12    *emotional disorders (SED) into a system of residentially based*  
13    *services.*

14    *(b) The plan developed pursuant to subdivision (a) shall be*  
15    *submitted to the Legislature on or before July 1, 2008, and shall*  
16    *include recommendations for specific statutory changes*  
17    *necessary for its implementation. It shall also include a fiscal*  
18    *impact statement and a specific implementation timetable, and*  
19    *shall identify any necessary regulatory changes.*

20    *(c) The plan shall reflect input from public and private*  
21    *nonprofit stakeholders, including, but not limited to,*  
22    *representatives of all of the following: the state departments of*  
23    *Social Services, Mental Health, Education, Alcohol and Drug*  
24    *Programs, and Corrections and Rehabilitation; county child*  
25    *welfare, probation, mental health, and alcohol and drug*  
26    *programs; local education authorities; current and former foster*  
27    *youth; parents of foster children or youth and children or youth*  
28    *with SED; private nonprofit agencies operating group homes;*  
29    *children's advocates; and other interested parties.*

30    *(d) The plan shall be based on the reports delivered to the*  
31    *Legislature pursuant to Section 75 of Chapter 311 of the Statutes*  
32    *of 1998 by the Steering Committee for the Reexamination of the*  
33    *Role of Group Care in a Family-Based System of Care in June*

1 2001 and August 2002, and the “Framework for a New System  
2 for Residentially Based Services in California” published in  
3 March, 2006.

4 (e) The department may employ an outside consultant with  
5 demonstrated national expertise in statewide foster care and  
6 residential systems to assist in the development of the plan and  
7 may make available planning grants to counties for the  
8 development and testing of proposals for alternative program  
9 and funding models pursuant to Section 18987.72.

10 (f) Along with redefining and improving the role of group  
11 care, it is also the intent of the Legislature that state agencies,  
12 counties, and private nonprofit agencies continue to work in  
13 partnership to develop additional community-based services that  
14 will make it possible for more children and youth to be safely and  
15 effectively served in their own homes or in another family-living  
16 situation with a relative, guardian, foster family, or adoptive  
17 family.

18 18987.71. (a) (1) For purposes of this chapter,  
19 “residentially based services” means behavioral or therapeutic  
20 interventions delivered in nondetention group care settings in  
21 which multiple children or youth live in the same housing unit  
22 and receive care and supervision from paid staff.

23 (2) The plan developed pursuant to Section 18987.7 shall be  
24 based upon an understanding that residentially based services  
25 are most effectively used as intensive, short-term interventions  
26 when children have unmet needs that create conditions that  
27 render them or those around them unsafe, or that prevent the  
28 effective delivery of needed services and supports provided in the  
29 children’s own homes or in other family settings, such as with a  
30 relative, guardian, foster family, or adoptive family.

31 (b) The plan developed pursuant to Section 18987.7 shall do  
32 all of the following:

33 (1) Require that a program offering residentially based  
34 services establish a safe, stable, and structured living  
35 environment in which behavioral or therapeutic interventions  
36 can be provided in order to allow children or youth to transition  
37 safely to their own homes or another permanent or stable family  
38 setting. A program shall also provide to families or other  
39 primary care givers, or assist them in obtaining, services and

1 *supports they may need to help them successfully prepare for and*  
2 *retain the children or youth in their family settings.*

3 *(2) Require that a program offering residentially based*  
4 *services include interventions that include all of the following:*

5 *(A) Environmental interventions that establish a safe, stable,*  
6 *and structured living situation in which children or youth can*  
7 *receive the comfort, attention, structure, and guidance needed to*  
8 *help them reduce the intensity of conditions that led to their*  
9 *placement in the program so that their caregivers can identify*  
10 *and address the factors creating those conditions.*

11 *(B) Intensive treatment interventions that facilitate the rapid*  
12 *movement of children or youth toward connection or*  
13 *reconnection with appropriate and natural home, school, and*  
14 *community ecologies by helping them and their families find*  
15 *ways to mitigate the conditions that led to their placement in the*  
16 *program with positive and productive alternatives.*

17 *(C) Parallel, predischarge community-based interventions that*  
18 *help family members, and other people in the social ecologies*  
19 *that children and youth will be joining or rejoining, to prepare*  
20 *for connection or reconnection. These preparations should be*  
21 *initiated upon placement and proceed apace with the*  
22 *environmental interventions being provided within the residential*  
23 *setting.*

24 *(D) Follow-up, postdischarge support and services, consistent*  
25 *with the child's case plan, provided as needed after children or*  
26 *youth have exited the residential component and returned to their*  
27 *own family or to another family living situation in order to*  
28 *ensure the stability and success of the connection or*  
29 *reconnection with home, school, and community.*

30 *(3) Include all of the following elements:*

31 *(A) Clear and objective placement criteria to be applied when*  
32 *determining whether a child's and family's circumstances are*  
33 *such that placement of the child in a program offering*  
34 *residentially based services is necessary in order to address the*  
35 *unmet needs of the child that prevent the child and family from*  
36 *receiving and benefitting from assistance provided in the child's*  
37 *own home or in a family setting with a relative, guardian, foster*  
38 *family, or adoptive family.*

39 *(B) The identification of the comprehensive assessment*  
40 *process to be used by county placement agencies when deciding*

1 *whether placement in a program providing residentially based*  
2 *services is the option most likely to effectively meet the needs of a*  
3 *child or youth, and his or her family, and help him or her achieve*  
4 *the outcomes that are the goals of the intervention.*

5 *(C) The identification of the process to be used by county*  
6 *placement agencies and private, nonprofit agencies operating*  
7 *programs that provide residentially based services to insure that*  
8 *the specific program chosen for a child or youth is able to*  
9 *provide the types and level of care and services needed to meet*  
10 *the needs of that child or youth. This may involve the*  
11 *development of categories for residentially based services*  
12 *programs based on the target population of children or youth*  
13 *they are designed to serve and the types and levels of care and*  
14 *services they provide.*

15 *(D) The identification of processes and procedures that will*  
16 *ensure the active involvement of children or youth and their*  
17 *families in the initial development and ongoing management of*  
18 *plans of care and the delivery of services and treatment.*

19 *(E) The identification of a functional system for collaborative*  
20 *decisionmaking regarding the use of residentially based services*  
21 *in each county that ensures full participation by the county*  
22 *placement agency, other public agencies involved with providing*  
23 *or funding services needed by the children and their families, the*  
24 *residentially based services programs, and other involved*  
25 *parties, including children or youth and their families.*

26 *(F) The development of administrative mechanisms, such as*  
27 *community care licensing, to ensure that the residentially based*  
28 *services programs and the facilities they use meet appropriate*  
29 *health and safety standards. These standards should not create*  
30 *inappropriate barriers that inhibit the children or youth in*  
31 *placement from engaging in activities that are necessary for their*  
32 *development.*

33 *(G) The development of administrative mechanisms to ensure*  
34 *that each agency offering residentially based services programs*  
35 *demonstrates its programmatic and organizational competencies*  
36 *with respect to its mission, values, administration, management,*  
37 *staffing, and quality assurance.*

38 *(H) The development of administrative mechanisms to ensure*  
39 *that each agency offering residentially based services programs*  
40 *demonstrates its competency in all of the following phases of its*

1 service planning and delivery system: engagement, planning,  
2 implementation, coordination, and evaluation and quality  
3 improvement.

4 (I) The establishment of criteria to ensure that discharge plans  
5 and timelines are developed concurrently with treatment and  
6 service plans at the time of placement, and are subsequently  
7 monitored and updated based on the progress of the children or  
8 youth and their families' circumstances, with the goal of  
9 reconnecting the children or youth with their families, schools,  
10 and communities.

11 (J) The establishment of criteria to ensure that service and  
12 discharge planning include the identification and preparation of  
13 relatives, guardians, adoptive families, or foster families with  
14 whom the children or youth can live either on a permanent basis,  
15 or until they can be reunified with their parents, in those cases  
16 when it is not possible to reunify children or youth with their own  
17 parents or other appropriate family.

18 (K) The creation and definition of specific and objective  
19 outcome indicators, and the development of tools and systems for  
20 measuring them, to reflect progress made by children or youth  
21 placed in programs offering residentially based services toward  
22 the goals of safety, permanence, and well-being within the  
23 context of the California Child Welfare Outcomes and  
24 Accountability System.

25 (L) The development of administrative mechanisms to ensure  
26 that private nonprofit agencies operating residentially based  
27 services programs use the funding they receive through the Aid  
28 to Families with Dependent Children-Foster Care (AFDC-FC)  
29 program (Art. 5 (commencing with Sec. 11400), Ch. 2, P. 3) and  
30 other public programs to provide quality care and services to the  
31 children or youth and their families, consistent with state  
32 requirements and county placement agreements.

33 (M) The development of a new methodology for providing  
34 funding through the AFDC-FC program for care, supervision,  
35 and social work activities, and the development of an additional  
36 funding mechanism to pay for the costs of parallel, pre-discharge  
37 community-based interventions and follow-up and postdischarge  
38 support, either as new components of the AFDC-FC program or  
39 as new separate funding streams. The new funding methodology

1 *for residentially based services programs shall do all of the*  
2 *following:*

3 *(i) Support the values and goals for residentially based*  
4 *services described above, including active child and family*  
5 *involvement, permanence, collaborative decisionmaking, and*  
6 *outcome measurement.*

7 *(ii) Ensure that quality care and effective services are*  
8 *delivered to appropriate children or youth at a reasonable cost*  
9 *to the public.*

10 *(iii) Ensure that payment levels are adequate to cover the*  
11 *reasonable cost of the private nonprofit agencies operating*  
12 *residentially based services programs, including the cost of*  
13 *hiring and retaining qualified staff to provide care and services*  
14 *to the children or youth and their families.*

15 *(iv) Facilitate compliance with state requirements and the*  
16 *attainment of federal and state performance objectives.*

17 *(v) Control overall program costs by providing incentives for*  
18 *the private nonprofit agencies to use the most cost-effective*  
19 *approaches for achieving positive outcomes for the children or*  
20 *youth and their families.*

21 *(vi) Facilitate the ability of the private nonprofit agencies to*  
22 *access other available public sources of funding and services to*  
23 *meet the needs of the children or youth placed in their*  
24 *residentially based services programs, and the needs of their*  
25 *families.*

26 *(vii) Enable the braiding of various funding streams necessary*  
27 *to meet the full range of services needed by foster children or*  
28 *youth in residentially based services programs, with particular*  
29 *reference to funding for mental health treatment services through*  
30 *the Medi-Cal Early and Periodic Screening, Diagnosis, and*  
31 *Treatment program.*

32 *(viii) Maximize federal financial participation to the extent*  
33 *that it does not inordinately impede the effective delivery of*  
34 *services to children or youth and families, and the achievement*  
35 *of positive outcomes.*

36 *(ix) Include provisions for effective administrative oversight*  
37 *and enforcement mechanisms in order to ensure programmatic*  
38 *and fiscal accountability.*

39 *(4) Identify and define the modifications necessary to address*  
40 *the particular and diverse requirements associated with children*



1 or youth placed for residentially based services by each major  
2 component of the system, including child welfare, probation,  
3 mental health, and education.

4 (5) Identify and define in each of the elements adaptations  
5 necessary to support the effective and efficient operation of  
6 residentially based services programs designed to provide care,  
7 supervision, services, and treatment for children or youth with  
8 similar challenges or conditions, including, but not limited to,  
9 programs designed primarily to serve any of the following:

10 (A) Children and youth in need of emergency shelter and  
11 assessment.

12 (B) Pregnant or parenting youth.

13 (C) Older youth preparing to emancipate from the foster care  
14 system.

15 (D) Youth in the juvenile justice system.

16 (E) Youth with substance abuse problems.

17 (F) Juvenile sex offenders.

18 (G) Children and youth with emotional disturbance or mental  
19 illness.

20 (H) Lesbian, gay, bisexual, transgender, or questioning youth.

21 (6) Use the existing level of federal, state, and county funding  
22 in a more cost-effective manner than under current law by  
23 improving the up-front assessment and placement processes, and  
24 permitting private nonprofit agencies to provide services and  
25 support to families while their children or youth are in placement  
26 and after they are discharged, with the goals of reducing the  
27 average length of stay in foster care, reducing reentries into  
28 foster care, and achieving better long-term outcomes.

29 (7) Use the savings created by reducing the average length of  
30 stay in foster care, and in reducing reentries into foster care, to  
31 pay adequate rates under the AFDC-FC program to the private  
32 nonprofit agencies for the time that the children or youth are  
33 participating in their residential programs. These savings shall  
34 also be used to pay the private nonprofit agencies for costs  
35 associated with new predischarge family support and  
36 postdischarge services, to fund county implementation of more  
37 effective up-front assessment and placement procedures, and to  
38 fund other related community-based services and support.

39 18987.72. (a) In order to obtain knowledge and experience  
40 with which to inform the process of developing and implementing

1 *the plan for residentially based services, pursuant to Section*  
2 *18987.7, the State Department of Social Services shall encourage*  
3 *counties and private nonprofit agencies to develop voluntary*  
4 *agreements to test alternative program design and funding*  
5 *models for transforming existing group home programs into*  
6 *residentially based services programs in order to meet the*  
7 *diverse needs of children or youth and families in the child*  
8 *welfare, juvenile justice, and mental health systems.*

9 *(b) With the approval of the department, any county and*  
10 *private nonprofit agency may enter into and implement a*  
11 *voluntary agreement to transform all or part of an existing group*  
12 *home program into a residentially based services program, if the*  
13 *agreement satisfies all of the following requirements:*

14 *(1) It incorporates and addresses all of the components and*  
15 *elements for residentially based services described in Sections*  
16 *18987.7 and 18987.71.*

17 *(2) It reflects active collaboration among the private nonprofit*  
18 *agency that will operate the residentially based services program*  
19 *and county departments of social services, mental health, or*  
20 *juvenile justice, alcohol and drug programs, county offices of*  
21 *education, or other public entities, as appropriate, to ensure that*  
22 *children, youth, and families receive the services and support*  
23 *necessary to meet their needs.*

24 *(3) It includes provisions for the preparation of an annual*  
25 *evaluation report, to be prepared jointly by the county and the*  
26 *private nonprofit agency. The evaluation report shall include*  
27 *analyses of the outcomes for children and youth, including*  
28 *achievement of permanency, involvement of children or youth*  
29 *and their families, client satisfaction, the use of the program by*  
30 *the county, the operation of the program by the private nonprofit*  
31 *agency, payments made to the private nonprofit agency by the*  
32 *county, and actual costs incurred by the nonprofit agency for the*  
33 *operation of the program. The county shall send a copy of each*  
34 *annual evaluation report to the director, and the director shall*  
35 *make these reports available to the Legislature upon request.*

36 *(4) It includes provisions that permit amendments,*  
37 *modifications, and extensions of the agreement to be made, with*  
38 *the mutual consent of both parties, based on the evaluations*  
39 *described in paragraph (3), and on the experience and*

1 *information acquired from the implementation and the ongoing*  
2 *operation of the program.*

3 *(5) It is consistent with the county's System Improvement Plan*  
4 *developed pursuant to the California Child Welfare Outcomes*  
5 *and Accountability System.*

6 *(c) (1) Upon request from a county, the director may waive*  
7 *regulatory provisions governing child welfare services,*  
8 *AFDC-FC payments, or the operation of programs licensed as*  
9 *group homes in order to enable a county and a private nonprofit*  
10 *agency to implement an agreement described in subdivision (b).*

11 *(2) Notwithstanding Sections 11460 and 11462, and any other*  
12 *provisions of this code governing payments under the AFDC-FC*  
13 *program, upon request from a county, the director may also*  
14 *approve the use of alternative funding models under the*  
15 *AFDC-FC program for care and supervision, social work*  
16 *activities, and parallel predischarge community-based*  
17 *interventions for families, as described in subparagraph (C) of*  
18 *paragraph (2) of subdivision (b) of Section 18987.71, and*  
19 *follow-up post-discharge support and services for children and*  
20 *their families, as described in subparagraph (D) of paragraph*  
21 *(2) of subdivision (b) of Section 18987.71, in order to enable a*  
22 *county and a private nonprofit agency to implement an*  
23 *agreement described in subdivision (b).*

24 *(3) A waiver granted by the director pursuant to paragraph*  
25 *(1), or an approval of an alternative funding model pursuant to*  
26 *paragraph (2), shall be applicable only to the development,*  
27 *implementation, and ongoing operation of a residentially based*  
28 *services program and related county activities provided under*  
29 *the terms of the agreement and for the duration of the agreement,*  
30 *and shall be granted only when all of the following apply:*

31 *(A) The agreement promises to offer a worthwhile test related*  
32 *to the development, implementation, and ongoing operation of a*  
33 *residentially based services program as described in this*  
34 *chapter.*

35 *(B) Existing regulatory provisions or the existing AFDC-FC*  
36 *payment requirements, or both, impose barriers for the effective,*  
37 *efficient, and timely implementation of the agreement.*

38 *(C) The requesting county proposes to monitor the agreement*  
39 *for compliance with the terms of the waiver or the alternative*  
40 *funding model, or both.*

1     (D) Neither the waiver nor the alternative funding model will  
2     result in an increase in the costs to the General Fund for rate  
3     payments under the AFDC-FC program, measured over a period  
4     defined in the agreement. This would permit higher AFDC-FC  
5     rate payments to be made when children or youth are initially  
6     placed in a residentially based services program, with savings to  
7     offset these higher costs being achieved through shorter lengths  
8     of stay in foster care, or a reduction of reentries into foster care,  
9     as the result of the provision of predischarge support and  
10    postdischarge services to the children or youth and their  
11    families.

12    (d) In addition to the requirements set forth in subdivision (b),  
13    the voluntary agreements shall do all of the following:

14    (1) Provide that, to the extent that some of the care, services,  
15    and other activities associated with a residentially based services  
16    program operated under an agreement described in subdivision  
17    (b) are not eligible for federal financial participation as foster  
18    care maintenance payments under Part E of Title IV of the  
19    federal Social Security Act (42 U.S.C. Sec. 670 et seq.), but may  
20    be eligible for federal financial participation as administration  
21    or training, or may be eligible for federal financial participation  
22    under other programs, including, but not limited to, Title XIX of  
23    the federal Social Security Act (42 U.S.C. Sec. 1396 et seq.), the  
24    appropriate state departments shall take measures to obtain that  
25    federal funding.

26    (2) Provide that, prior to approving any waiver or alternative  
27    funding model pursuant to subdivision (c), the director shall  
28    make a determination that the design of the residentially based  
29    services program to be operated under the agreement described  
30    in subdivision (b) would ensure the health and safety of children  
31    or youth to be served.

32    SEC. 2. There is hereby appropriated the sum of five hundred  
33    thousand dollars (\$500,000) from the General Fund to the  
34    California Health and Human Services Agency for the purpose of  
35    employing an outside consultant pursuant to subdivision (e) of  
36    Section 18987.7 of the Welfare and Institutions Code, as added  
37    by Section 1 of this act.

38    ~~SECTION 1. The Legislature finds and declares all of the~~  
39    ~~following:~~

1 (a) ~~The federal Food and Drug Administration (FDA) operates~~  
2 ~~a voluntary reporting system for adverse drug reactions known as~~  
3 ~~the MedWatch system.~~

4 (b) ~~The FDA currently estimates that only 10 percent of the~~  
5 ~~adverse drug reactions or events that occur each year are reported~~  
6 ~~to the FDA.~~

7 (c) ~~Given the prevalence of pharmaceuticals and their use for~~  
8 ~~treatment of hundreds of chronic diseases and conditions, and~~  
9 ~~given recent highly publicized instances of commonly used~~  
10 ~~prescription drugs being taken off the market due to safety~~  
11 ~~concerns that were discovered after the drugs were approved for~~  
12 ~~use, the systematic underreporting of adverse drug events~~  
13 ~~represents a serious public health problem.~~

14 (d) ~~Requiring licensed health professionals of organizations to~~  
15 ~~report adverse drug events to the FDA would increase the~~  
16 ~~amount of data available to the FDA about adverse drug~~  
17 ~~reactions, thereby enabling the FDA to discern problems with~~  
18 ~~drugs that arise after they are approved and to take action to~~  
19 ~~protect the public health in a more timely manner.~~

20 SEC. 2. ~~Article 7 (commencing with Section 111657) is~~  
21 ~~added to Chapter 6 of Part 5 of Division 104 of the Health and~~  
22 ~~Safety Code, to read:~~

23  
24 Article 7. Adverse Event Reporting  
25

26 111657. (a) ~~A licensed health professional, including, but not~~  
27 ~~limited to, a physician and surgeon, dentist, or pharmacist, and a~~  
28 ~~health facility, including, but not limited to, a hospital or clinic,~~  
29 ~~shall report all suspected serious adverse drug events that are~~  
30 ~~spontaneously discovered or observed in medical practice to~~  
31 ~~MedWatch, the drug safety information and adverse event~~  
32 ~~reporting program operated by the federal Food and Drug~~  
33 ~~Administration.~~

34 (b) ~~For purposes of this section, serious adverse drug events~~  
35 ~~shall include adverse health outcomes involving patients that~~  
36 ~~result in death, life-threatening conditions, hospitalization,~~  
37 ~~disability, congenital anomaly, or required intervention to~~  
38 ~~prevent permanent impairment or damage.~~

39 (c) ~~Any health professional or health facility that is required to~~  
40 ~~report an adverse drug event pursuant to this section shall do so~~

1 ~~using the FDA 3500 Voluntary form developed by the federal~~  
2 ~~Food and Drug Administration for MedWatch.~~  
3 ~~111658. A licensed health professional or health facility that~~  
4 ~~violates any provision of this article shall not be subject to the~~  
5 ~~penalties and remedies outlined in Chapter 8 (commencing with~~  
6 ~~Section 111825) or any other provision of law. Nothing in this~~  
7 ~~section affects otherwise existing duties, rights, or remedies~~  
8 ~~under the law.~~

O